UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,992	10/19/2001	Volkhard Lindner	53689-5006-01	3105

28977 7590 03/25/2004

MORGAN, LEWIS & BOCKIUS LLP
1701 MARKET STREET
PHILADELPHIA, PA 19103-2921

EXAMINER	
HADDAD, MAHER M	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 03/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/045,992	LINDNER ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-55 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Restriction Requirement

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 2-3, 6-15, 19-20 and 34-36, drawn to an isolated nucleic acid of SEQ ID NO:1 encoding rat REMODELIN, fragment thereof; vectors, host cells and a kit, classified in Class 536, subclass 23.5; Class 435, subclasses 69.1, 455, 252.3, 320.1, and 810.

II. Claims 2-3, 6-15, 19-20, and 34-36, drawn to an isolated nucleic acid of SEQ ID NO:3 encoding human REMODELIN, fragment thereof; vectors, host cells and a kit, classified in Class 536, subclass 23.5; Class 435, subclasses 69.1, 455, 252.3, 320.1 and 810.

III. Claims 5, and 21, drawn to an isolated polypeptide of SEQ ID NO:2; classified in Class 530, subclasses 395.

IV. Claims 5, and 21, drawn to an isolated polypeptide of SEQ ID NO:4; classified in Class 530, subclasses 395.

V. Claims 5, and 21, drawn to an isolated polypeptide of SEQ ID NO:5; classified in Class 530, subclasses 395.

VI. Claims 17-18, drawn to an antibody against SEQ ID NO:2; classified in Class 530, subclass 387.3.

VII. Claims 17-18, drawn to an antibody against SEQ ID NO:4; classified in Class 530, subclass 387.3.

VIII. Claims 17-18, drawn to an antibody against SEQ ID NO:5; classified in Class 530, subclass 387.3.

IX. Claim 22, drawn to a non-human mammal comprising the isolated nucleic SEQ ID NO:1, classified in Class 800, subclass 8.

X. Claim 22, drawn to a non-human mammal comprising the isolated nucleic SEQ ID NO:3, classified in Class 800, subclass 8.

XI. Claims 23-24, drawn a method of treating a disease mediated by abnormal expression of REMODELIN as it reads on SEQ ID NO: 1, wherein said disease is impaired wound healing, classified in Class 514, subclass 44.

XII. Claims 23-24, drawn a method of treating a disease mediated by abnormal expression of REMODELIN as it reads on SEQ ID NO: 3, wherein said disease is impaired wound healing, classified in Class 514, subclass 44.

XIII. Claims 23-24, drawn a method of treating a disease mediated by abnormal expression of REMODELIN as it reads on SEQ ID NO: 1, wherein said disease is fibrosis of an organ, classified in Class 514, subclass 44.

XIV. Claims 23-24, drawn a method of treating a disease mediated by abnormal expression of REMODELIN as it reads on SEQ ID NO: 3, wherein said disease is fibrosis of an organ, classified in Class 514, subclass 44.

XV. Claims 23-24, drawn a method of treating a disease mediated by abnormal expression of REMODELIN as it reads on SEQ ID NO: 1, wherein said disease is ectopic ossifcation, classified in Class 514, subclass 44.

XVI. Claims 23-24, drawn a method of treating a disease mediated by abnormal expression of REMODELIN as it reads on SEQ ID NO: 3, wherein said disease is ectopic ossifcation, classified in Class 514, subclass 44.

XVII. Claims 23-24, drawn a method of treating a disease mediated by abnormal expression of REMODELIN as it reads on SEQ ID NO: 1, wherein said disease is hypertrophic scar formation, classified in Class 514, subclass 44.

XVIII. Claims 23-24, drawn a method of treating a disease mediated by abnormal expression of REMODELIN as it reads on SEQ ID NO: 3, wherein said disease is hypertrophic scar formation, classified in Class 514, subclass 44.

XIX. Claims 25-26, drawn to a method of diagnosing arterial resternosis, classified in Class 435, subclass 7.1.

XX. Claim 27, drawn to a method of diagnosing negative remodeling, classified in Class 435, subclass 7.1.

XXI. Claims 28, drawn to a method of diagnosing fibrosis, classified in Class 435, subclass 7.1.

XXII. Claims 29 and 31, drawn to a method of identifying a compound that affects expression of REMODELIN in a cell, classified in Class 435, subclass 7.1.

XXIII. Claims 30 and 32, drawn to a compound identified by claim 29 or claim 31, classified in Class 530, subclass 395.

XXIV. Claim 33, drawn to a method of identifying a compound that affects TGF-β signaling, classified in Class 435, subclass 7.1.

XXV. Claims 37-41, drawn to a kit comprising a REMODELIN expression-inhibiting amount of an inhibitor of REMODELIN expression, wherein the REMODELIN expression-inhibitor is not an isolated nucleic acid encoding REMODELIN, or fragment thereof, classified in Class 530, subclass 350.

XXVI. Claim 42, drawn to a method of increasing REMODELIN expression with a REMODELIN expression increasing amount of TGF-β, classified in Class 424, subclass 198.1.

XXVII. Claim 43, drawn to a method of reducing REMODELIN expression with a REMODELIN expression reducing amount of TGF-β receptor type II, classified in Class 514, subclass 8.

XXVIII. Claims 44-46, drawn to a method of affecting cellular gene expression with a nucleic acid encoding REMODELIN, classified in Class 514, subclass 44.

XXIX. Claim 47, drawn to a method of affecting cellular gene expression with a nucleic acid antisense to a nucleic acid encoding REMODELIN, classified in Class 514, subclass 44.

XXX. Claims 48-49, drawn to a method of treating bone disease with a REMODELIN expression-inhibiting amount of an inhibitor of REMODLEN expression, classified in Class 514, subclass 8.

XXXI. Claims 50-51, drawn to a method of treating cartilage disease with a REMODELIN expression-inhibiting amount of an inhibitor of REMODLEN expression, classified in Class 514, subclass 8.

XXXII. Claims 52-53, drawn to a method of diagnosing a bone disease, classified in Class 435, subclass 7.1.

XXXIII. Claims 54-55, drawn to a method of diagnosing a collagen disease, classified in Class 435, subclass 7.1.

Claim 1 is a linking claim and will be examined along with any one of elected groups I-II.

Claim 4 is a linking claim and will be examined along with any one of elected groups III-V.

Claim 16 is a linking claim and will be examined along with any one of elected groups VI-VIII.

2. Groups I-X, XXIII and XXV are different products. Nucleic acids, polypeptides, antibodies to the polypeptides, transgenic non-human mammal and inhibitors of REMODELIN expression differ with respect to their structures and physicochemical properties; therefore each product is patentably distinct.

3. Groups XI-XXII and XXVI-XXXIII are different methods. A method for treating, a method of diagnosing and a method identifying differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

4. Groups I/XI, I/XIII, I/XV, I/XVII, I/XXVII, I/XXIX, II/XII, II/XIV, II/XVI and II/XVIII and XXV/XXX-XXXI are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid of Groups I-II can be used as hybridization probe, in addition to the methods of treating recited.

5. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper. Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention.

Species Election

6. Irrespective of whichever group applicant may elect, applicant is further required under 35 US 121 (1) to elect a single disclosed species to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

A. If Group XXXI or XXXIII is elected, applicant is required to elect a specific collagen disease such as a) osteogenesis, b) imperfecta, c) dystrophic epidermolysis bullosea or d) Bethlem myopath. These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter.

7. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

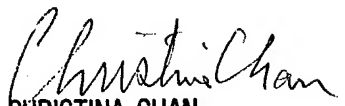
In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maher Haddad, Ph.D.
Patent Examiner
Technology Center 1600
March 22, 2004



CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600